Supreme Court, U.S.
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No. 06-830

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF AMICI CURIAE OF 41 PROFESSORS OF ECONOMICS, BUSINESS AND LAW IN SUPPORT OF GRANTING THE PETITION

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INTEREST OF AMICI

Amici are professors of business, economics and law who have written extensively on innovation, intellectual property, competition and antitrust. Amici have no stake in the outcome of this case.[1] (A list of signatories is in Appendix A). Our sole interest in this case is that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

ARGUMENT

I. The Second Circuit Opinion Is Unprecedented and Conflicts With the Approaches of the Sixth Circuit, the Eleventh Circuit, and the Federal Trade Commission

The Second Circuit's opinion in this case contains fundamental errors of economic reasoning and would shield many anti-competitive agreements from the reach of antitrust law, causing great harm to competition, to U.S. consumers, and (by unjustifiably raising the costs of needed medicines) to public health. According to the panel majority, an agreement between a patent holder and an alleged infringer to settle their patent litigation cannot violate the antitrust laws so long as the patent litigation was not a sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the scope of the patent. Such settlements are considered *per se* legal even if, as here, the patent holder makes a substantial payment to the alleged infringer in exchange for the latter's promise not to sell the patented product independently during the patent's lifetime, and even if the patent in question is "fatally weak." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212 (2d Cir. 2006). In so holding, the panel majority has adopted a rule of near per se *legality* for conduct that seems anticompetitive on its face.

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1. We certify that no party other than the signatories has paid for or participated in the drafting of this brief. We have received the consent of all parties to the filing of this brief.

The panel's rule is far outside the mainstream of judicial and academic analysis of settlements that involve such payments and promises ("exclusionary settlements"). The Sixth Circuit considers such agreements per se *illegal*, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the Federal Trade Commission considers them presumptively anticompetitive, *see In re Schering Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), while the Eleventh Circuit applies its own test that inquires into the underlying validity of the patent before characterizing the conduct, *see Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). No other circuit has applied the panel majority's approach. Similarly, although academic commentators are divided on the treatment to be accorded such settlements, they uniformly agree they should not be consider per se *legal*. Some, including some of the undersigned, have written that settlements involving a large payment from the patent holder to the challenger should be presumptively anti-competitive.[2] Others have argued for applying the rule of reason[3] or for

2. *See, e.g.*, 1 *Herbert Hovenkamp et al., IP and Antitrust* §7.4e2, at 7-38 to 39 (2005 Supp.); Scott A. Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *NYU L. Rev.* 1553 (2006); Herbert Hovenkamp et al., "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minn. L. Rev.* 1719 (2003); Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 *Rand J. Econ.* 391 (2003); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in 4 *Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Mark A. Lemley & Carl Shapiro, "Probabilistic Patents," 19 *J. Econ. Perspectives* 75 (2005); Joseph Farrell & Carl Shapiro, "How Strong Are Weak Patents?" Competition Policy Center Working Paper 05-054 (2005), available at *http://repositories.cdlib.org/iber/cpc/CPC05-54/*.

3. Daniel A. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 *Fla. L. Rev.* 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, "Are Settlements of Patent Disputes Illegal Per Se?", 47 *Antitrust Bull.* 491, 534-38 (2002).

per se illegality.[4] Other courts and commentators note that the antitrust analysis is more complex for settlements that generate offsetting benefits to consumers, e.g., those involving negotiated entry dates or patent licenses.[5] It is ironic that the panel majority—the first Court of Appeals to apply such a rule—justified its unprecedented decision by saying that "[i]t is too late in the journey for us to alter course." *Id.* To the contrary, it is the panel majority that sets out on a new and dangerous course.

The amici differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements. We need not resolve those differences in this case because we all agree that exclusionary settlements can state a claim under the antitrust laws. The panel majority took the unprecedented step of concluding on a motion to dismiss that exclusionary settlements can almost never be illegal. As a result, unless the opinion is reversed case law in the Second Circuit will never develop to distinguish pro- and anti-competitive settlements. Worse, without review by this Court businesses will lack guidance on the legality of their conduct because fundamental conflicts between the approaches of the different circuits will persist.

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4. Maureen A. O'Rourke & Joseph F. Brodley, "An Incentives Approach to Patent Settlements," 87 *Minn. L. Rev.* 1767, 1781-82 (2003).

5. *Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (finding that a cross-license agreement did not violate the antitrust laws); 1 *Hovenkamp et al., supra* note 2, at §7.4e3 (discussing delayed entry settlements).

II. Exclusion Payments Are Generally Anticompetitive

A. The Settling Parties Have an Incentive to Preserve Monopoly Profits in Ways That Harm Consumers, Competition, and Public Health

A monopolist and any uniquely strong or early-arriving potential entrant have a strong incentive to enter into an exclusionary settlement. The settlement preserves the monopoly and thus keeps prices and profits high. In the Hatch-Waxman setting, where the first generic to file an ANDA is entitled to a period of statutory exclusivity, the patent owner's incentive to settle with that first generic is particularly great.

The fact that the *parties* to the settlement can maximize their profits through an exclusion payment does not mean that such a settlement is in the *public* interest. That extra profit comes from somewhere. In the case of an exclusionary settlement under the Hatch-Waxman Act, it comes from the pockets of the elderly and other users of medicines who would be able to purchase lower cost medications if the generic's legal arguments were successful. Absent the settlement, the patent litigation might reveal that the patent was invalid or not infringed, leading to more competition and lower prices. With an exclusion payment, the pharmaceutical patentee buys assurance that its patent will not be invalidated—something the patent law alone does not give and that the Hatch Waxman Act did not contemplate. It uses some of this extra monopoly profit obtained by avoiding what might have been a successful legal challenge to pay off the potential competitor. Such a settlement denies consumers the benefits of enhanced competition that Congress intended to result if the patent were found invalid or not infringed. Those benefits aren't merely a windfall from abrogation of a legitimate patent. On the contrary, they result from the right to invalidate patents the government should never have issued. Discovering the truth about the patent's validity or scope in no way threatens the rewards to properly patented innovations that in fact are infringed.

Under the panel majority's opinion, the monopolist and potential entrant are permitted to enter into an exclusionary settlement that denies these benefits to consumers *regardless* of contemporaneous evidence about the likelihood that the patent will be found invalid or not infringed. In particular, the majority ignored evidence in the form of a large exclusionary payment from the patent holder to the potential rival, surely an indication that the patent holder considered its patent to be weak. The panel even ignored the fact that at the time of settlement the patent in question had been held invalid in the district court. The interests of consumers are given no weight at all in the majority opinion's calculus. Nor is the public interest in testing weak patents given any weight at all.

B. The Panel Majority Wrongly Assumes That Every Patent Holder Has an Absolute Right to a Monopoly

The panel majority acknowledges that "there is something on the face of it that does seem 'suspicious'" about a large reverse payment, *Tamoxifen Citrate*, 466 F.3d at 208, but goes on to say:

> We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.

Id.

Here and at other key points, the majority falls back on the *assumption* that the patent holder, by virtue of the patent grant, has an absolute right to enter into an exclusionary settlement, simply because of the presumption of validity afforded to patents. But that assumption is false. A patent

does not confer a certain legal right. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Rather, it reflects an initial judgment by the Patent and Trademark Office that the invention is patentable. That judgment is made after only a cursory scrutiny. When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued. As this Court put it in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969):

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity. Consequently, it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue ...

Id. at 670. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found invalid.[6] The number is even higher in pharmaceutical cases – an FTC study of all pharmaceutical patent litigation between 1992 and 2000 found that the patent owner lost in 73% of the cases. *http://ftc.gov/os/2006/07/P052103BarrierstoGeneric EntryTestimonySenate07202006.pdf* (page 10). Further, in cases such as this one, the fact that the patent owner must pay the accused infringer a large sum of money to stay out of the market – or even just to delay entry – is strong evidence that the patent owner sees the patent as likely to be held invalid or not infringed. The patent holder in such situations rationally understands that to protect the value of a monopoly *to which it*

6. John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 29 *Am. Intell. Prop. L. Ass'n. Q.J.* 185 (1998) (studying all patent validity litigation over an 8-year period and finding that 46% of all patents litigated to judgment were held invalid).

was never in fact and in law entitled, it must share some of the ill-gotten revenue with those who would otherwise invalidate it. They in turn have every incentive to settle in exchange for a share of the monopoly profits rather than to litigate.[7]

Where, as here, the case arises on a motion to dismiss, the courts must take as true plaintiffs' allegations that the Federal Circuit would likely have affirmed the district court's initial finding that the patent was invalid. If the patent can be proven invalid, the settlement can certainly be anticompetitive and thus should be subject to antitrust review.

The panel majority does not merely protect established rights of patent holders. Rather, by letting patent owners buy immunity from competition even with "fatally weak" patents, the majority has greatly expanded the patent holders' rights, turning a rebuttable (and often-rebutted) presumption into an irrebuttable one. A presumption of validity does not entitle a patentee to evade the test of patent litigation, any more than a criminal defendant's presumption of innocence entitles him to avoid trial. Allowing holders of weak patents thus to boost their profits is a poor way to encourage innovation, because by definition a weak patent often reflects no truly patentable innovation by the patentee. This Court has recognized "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear*, 395 U.S. at 670. That interest would be ill-served by allowing patentees to avoid any scrutiny of the validity or scope of application of their patents simply by agreeing to split their unwarranted profits with those who would challenge their right to those profits.

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7. Because the generic competitor can charge only a competitive price, it is possible for a settlement to provide a share of the monopoly price profits that convey to the generic competitor even greater profits than would be achieved by a successful lawsuit. Thus, the generic by settling avoids both litigation and commercial risks with higher potential returns – all at the expense of the consumer.

C. Permitting Exclusion Payments Is Not Necessary To Encourage Settlements in the Public Interest

The panel majority recognized that its rule shields troubling settlements from the antitrust laws, but concludes that the policy favoring settlement is so strong that it must extend even to "fatally weak" patents, "even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." *Tamoxifen Citrate*, 466 F.3d at 211.

We agree that there is a general policy in favor of settlement. We strongly disagree, however, with the majority's view that patent settlements must *always* be encouraged. That view confuses a general policy in favor of settlements that are in the public interest with an endorsement of a particular kind of settlement despite evidence that it is not in the public interest because of its anticompetitive effects. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. The social benefit of invalidating weak patents is well established in a line of this Court's cases. *See, e.g., United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969); *see also Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264 (1979) (referring to the "desirability of encouraging licensees to challenge the validity of patents"). A successful patent challenge provides valuable (and in the case of medicines necessary) benefits to third parties, including anyone who seeks to practice the patented

technology and consumers via enhanced competition.[8] The majority's rule dramatically undermines the important role of patent litigation in protecting the public from undeserved monopolies based on patents that may well prove to be invalid.

Reversing the panel majority's unprecedented and unwise rule of per se legality would by no means subject every patent settlement to an antitrust challenge. As noted above, some (including some of us) have suggested that a large exclusionary payment could be a suitable red flag, providing a limiting principle on such challenges; experience over time might suggest other approaches, but no such evolution can occur in the Second Circuit if the majority's holding stands.[9] The public interests involved warrant judicial evaluation of the facts of particular cases, and (if the Second Circuit holding is reversed) the courts can develop additional rules to provide guidance and to limit the burdens on the courts.

The majority is also wrong to assume that immunizing exclusion payments is necessary to encourage the many settlements that are in the public interest. Both generally and in the pharmaceutical context, patent owners and generics can and do settle patent cases without exclusion payments,

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8. *See, e.g.*, Joseph Farrell and Robert Merges, "Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help," 19 *Berkeley Tech L.J.* 943 (2004); Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Tech. L.J.* 667 (2004).

9. Nor could the Federal Trade Commission, the expert agency with jurisdiction over pharmaceutical patent settlements, develop such a rule. Because decisions of the Commission may be appealed to any regional circuit in which the defendant conducts business, Federal Trade Commission Act §5(c), if the Second Circuit's decision is allowed to stand the United States will effectively be subject to the rule of per se legality in all its cases involving exclusion payments.

by agreeing to let the generic enter in exchange for a license fee, by agreeing to delay entry without a payment, or in other ways. Indeed, the Federal Trade Commission, to which pharmaceutical patent settlements must now be reported, found 14 agreements settling patent litigation during 2003 and 2004, with none involving an exclusion payment. *See http://www.ftc.gov/opa/2005/01/drugsettlement.htm.* The fact that pharmaceutical companies can and do settle litigation without exclusion payments shows that there is no need to allow anticompetitive settlements in order to get the social benefits that most settlements provide.

III. This Case Presents a Question of Extraordinary Importance

This Court has long recognized that decisions on the validity of patents implicate important public interests. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945) ("A patent by its very nature is affected with a public interest."); *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965); *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."). Nowhere is that more true than in the area of pharmaceuticals. Consumers pay literally tens of billions of dollars more for patented drugs than they would for the same drugs if unpatented. Numerous studies have shown that higher drug prices result in consumers having to forego needed medicines. One study found that among people 65 and older, "a one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year."[10]

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10. Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219, 228 (Cont'd)

Where those patents are validly granted, the monopoly price arguably reflects a needed incentive to innovation. But where, as alleged in this case, a patent owner insulated a "fatally weak" patent from judicial scrutiny by entering into an anticompetitive agreement to avoid invalidation, it is the public that bears the cost of an *improperly* obtained monopoly on needed medicines. Anticompetitive settlements of this sort are all too common, and violate the legislative purpose behind the Hatch-Waxman Act, which was in part to encourage generic manufacturers to challenge weak patents. They will continue to proliferate unless and until the courts recognize the potential for anticompetitive harm and apply the antitrust laws accordingly. And in light of the Second Circuit's ruling in this case, only Supreme Court review can make that happen.

CONCLUSION

We urge the Court to grant certiorari and to reverse the decision of the Second Circuit Court of Appeals.

Respectfully submitted,

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(Cont'd)

(2000); *see also* Kaiser Family Foundation et al., *National Survey on Prescription Drugs* 4 (Sept. 2000) (reporting that 9% of U.S. citizens 65 and older have had to cut down on food or other basic necessities to pay for prescription drugs), *available at* http://www.pbs.org/newshour/health/prescriptions/summaryandchartpack.pdf.

APPENDIX

APPENDIX

List of Signatories[1]

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